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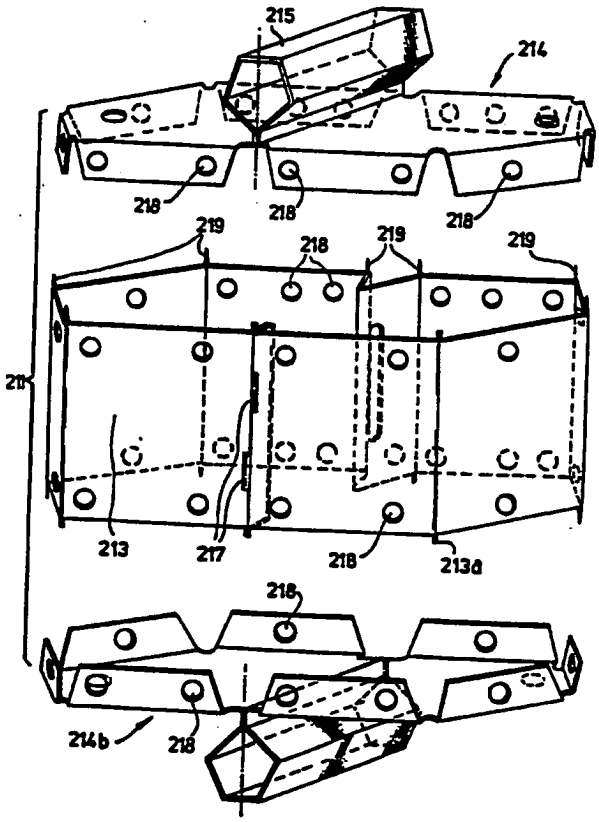
(57) Abstract

A prosthesis (111, 211) for use in bridging a gap between two bone sections, e.g. in replacing a diseased vertebra or disc, has a skeletal prosthetic element (213, 214), preparing to fit the prosthesis site in such manner as to provide a support in which bone can grow across the gap. The support (213, 214) may be packed with bone-growth supporting material (216) such as hydroxy apatite. The element (213, 214) can be made by CAD/CAM techniques and etching or electrochemical machining fold lines (242, 252, 253) in a metal plate plastically deformed to the required shape and can thus be custom made at the site of the operation and during its progress by CAD/CAM apparatus combined with etching or ECM equipment.



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PROSTHESES AND METHODS AND APPARATUS FOR MAKING SAME

This invention relates to prostheses for use in bridging a gap between two bone sections, and methods and apparatus for making such prostheses and surgical technique for bone replacement using such a prostheses.

In spinal surgery, it is in some circumstances required to remove a diseased vertebra or disc. The gap can be filled with bone taken from a rib, thigh, pelvis or other suitable region. This bone can be arranged to fuse with the neighbouring vertebrae as a result of natural bone growth on to the nucleus afforded by the transferred bone. This, however, is an invasive procedure to otherwise healthy bone and surrounding tissue elsewhere and complicates the surgical procedure. The bone is cut and located more or less by guesswork as to an appropriate shape and size, which is not an optimal procedure. It is inappropriate for much more than the replacement of a single vertebra or disc, so that for patients with more exensive damage there is no satisfactory surgical procedure.

Whilst the use of metal pins and plates is nowadays widespread in orthopedic surgery, no satisfactory manufactured prosthesis exists for gap-bridging in structural bones, in particular for the

replacement of vertebrae. The human spine comprises twenty four vertebrae, all different. Each of these vertebrae is unique to the invididual. So it is impractical to produce a set of standard vertebral prostheses.

The invention provides a prosthesis and methods and apparatus for making the same and a surgical technique which facilitates the repair and replacement of vertebrae or discs and also serves for bridging gaps in bones generally.

The invention comprises a method for making a prosthesis for use in bridging a gap between two bone sections comprising the steps of

a) predetermining the shape of the prosthesis required, and

b) preparing a skeletal prosthetic element to the required shape, in such manner as to provide a support in which bone can grow in the gap.

The skeletal prosthetic element may be packed with a bone-growth supporting material.

The bone-growth supporting material may comprise hydroxy-apatite. The skeletal prosthetic element may comprise any biocompatible material of suitable strength

and workability, such for example as metals including stainless steel and titanium.

The skeletal prosthetic element may be made by preparing a sheet material plate for plastic deformation to the predetermined shape and plastically deforming said prepared plate to said shape. The plate may be prepared with fold lines which may be made by etching or, more rapidly, by electro-chemical machining (ECM).

Thus the skeletal prosthetic element can be prepared as a strip or plate member from sheet material which can be bent to final shape by the surgeon in the course of the surgical procedure. The production of the bendable plate or strip can be rapidly effected in a variety of ways so that it becomes feasible to manufacture the prosthesis shortly before or even during the procedure to fit precisely the prosthetic site.

When the plate is prepared by etching or ECM, other features may be produced together with the fold lines, for example attachment spikes for engaging the prosthesis with neighbouring bone, and apertures for screws and pins, and the required perimeter of the prosthesis may also be produced by through-etching or ECM on the plate.

The plate may be prepared for etching or ECM by removing a resist layer; such layer may be removed mechanically as by a blade or rotary tool, or by an ultrasonic tool, or it may be removed by vaporisation as by an electrical discharge or laser. The resist layer may also be removed by selectively applying a chemical reagent or solvent.

The plate may be etched on both faces, for example for etching-through for perimeter-definition and for making spikes, screw holes and the like. Screws and/or pin apertures or holes may also be produced by a drill or punch or other purely mechanical means where convenient.

The etched or ECM-produced plate may be electropolished to remove sharp ridges or burrs.

The skeletal prosthetic element may be prepared by numerically-controlled tool means, which may operate in an etching or ECM process to prepare the plate for etching or ECM by selectively removing a resist layer, or which may operate directly on the plate to remove material therefrom as by drilling, routing etc.

In any event, the skeletal prosthetic element may be prepared according to instructions derived from a

programmed computer supplied with data specifying the shape of prosthesis required, and such computer may control the preparation of a plate from which the skeletal prosthetic element can be fashioned by bending along fold lines.

The computer may include CAD facility, in which X-ray photographs of the prosthesis site may be used.

Various improvements may be made on conventional ECM techniques which usually require a pre-shaped three dimensional tool to remove metal from a surface. Thus applying a resist layer to the workpiece as for normal etching techniques ensures that only the exposed metal areas are removed. Instead of applying the resist to the workpiece, however, the resist may be on the tool, and removed therefrom according to the desired pattern. The workpiece will be eroded more or less as if it had carried the resist, but there is no longer any need to remove the resist from the workpiece after the ECM operation, which cuts down the manufacturing time significantly.

Another technique involves interposing an apertured non-conducting layer e.g. of plastic sheet between the electrode and the workpiece. The apertures may be made by a rotating tool, a laser, an ultrasonic

cutter or in any other convenient manner. Here, again, there is no adhered resist layer to remove after the ECM.

The skeletal prosthetic element may be assembled from a plurality of sub-elements, and may be assembled from anchor plates and a spacer member joining the anchor plates and formed from a folded plate or plates. The spacer member may be cruciform and comprise meshing plates into which a bone growth supporting material, such as hydroxy-apatite, may be introduced into the prosthetic site; and final shaping and assembly may take place during surgical procedures.

The invention also comprises apparatus for making a prosthesis for use in bridging a gap between two bone sections at a prosthetic site comprising, in combination

a) means for predetermining the shape of the prosthesis required for the site, and

b) sheet material plate preparation means for preparing such plate for plastic deformation to a skeletal prosthetic element, in such manner as to provide a support in which bone can grow in the gap.

The sheet material preparation means may comprise etching or electro-chemical machining means,

and may also comprise electropolishing means. The preparation means may be numerically controlled and may comprise CAD means providing instructions for the preparation means, which may in turn comprise information input means for example for information derived from X-ray photographs.

The invention also comprises a novel prosthesis for use in bridging a gap between two bone sections comprising a skeletal prosthetic element adapted to the prosthetic site and capable of providing a support in which bone can grow in the gap. The element may be packed with a bone-growth supporting material, such as hydroxy-apatite.

The novel prosthesis may comprise folded sheet material, and may comprise attachment spikes adapted to engage bone either side of the gap.

A surgical technique using prostheses according to the invention can ensure safe repeatable results for both disc and complete vertebra replacement.

Prostheses for use in bridging a gap between two bone sections and methods and apparatus for making them and surgical procedure for implanting them according to the invention will now be described with reference to the accompanying drawings, in which :-

Figure 1 is a side view of a two-part disc replacement prosthesis;

Figure 2 is a top view of the prosthesis of Figure 1;

Figure 3 is a view of the top (a) and bottom (b) sections of the prosthesis of Figure 1 presented for engagement together;

Figure 4 is a side view of the top anchor plate of a vertebrate body replacement prosthesis;

Figure 5 is a side view of a cage member for use with the top anchor plate of Figure 4;

Figure 6 is a side view of a bottom anchor plate to fit the cage member of Figure 5;

Figure 7 is a plan view of an etched plate from which the anchor plates of the prosthesis of Figures 4 and 6 are produced;

Figure 8 is a plan view of an etched plate from which the cage member of Figure 5 is produced;

Figure 9 is a cross-sectional view of alternative cage members;

Figure 10 is a view of an etched or ECM blank for another type of bone replacement prosthesis;

Figure 11 is a view of the prosthesis made by bending the blank of Figure 10;

Figure 12 is a section on the line XII-XII of Figure 11;

Figure 13 is a section on the line XIII-XIII of Figure 11;

Figure 14 is a front and back side-on view of a swage tool;

Figure 15 is a diagrammatic illustration of a locking procedure carried out by the swage tool of Figure 14;

Figure 16 is a diagrammatic illustration of a CAD/CAM system for producing prepared sheet material plate ready for etching to produce the prostheses of Figure 1 to 11;

Figure 17 is a block diagram of a method for making the prostheses from the etched or electro-chemically machined plates of Figure 18;

Figure 18 to 20 are diagrammatic illustrations of electro-chemical machining techniques;

Figure 21 is a block diagram of a method for the production of a prosthesis ready for implantation from the prepared plate using the electro-chemical machining techniques of Figures 19 to 20.

Figure 22 to 37 are diagrammatic illustrations of sequential steps in a surgical technique for replacement of diseased vertebrate bodies with metal vertebra prostheses prepared as described in Figures 4 to 9.

The production of shaped articles from thin metal plates by etching fold lines and other features is already known, but as currently practised does not lend itself to rapid custom production. The resists in common use are photographic and the etching pattern is produced by photographing a master drawing, usually involving a reduction of scale so that high accuracy can be achieved. It is not economical to use this process to produce articles on a one-off basis and it would in any event be difficult to complete a 15 x 5 cm component from concept to finished state in less than five hours, even if the production were to be given priority and undivided attention. Normally, two or three days at least are required if the procedure is to fit within any ordered, commercial production schedule.

Photographic techniques may of course be developed in the future which will reduce the time and cost. Meanwhile, however, etched plates can be produced by other methods which do not suffer the disadvantages of the current photographic techniques.

Figures 1 to 3 illustrate a prosthesis 111 for use in bridging a gap between two bone sections, such for example as will occur when a vertebrate disc is removed.

Figures 4 to 9 illustrate prostheses 211 for use in bridging a gap between two bone sections, such for example as will occur when a vertebrate body is removed.

The disc prosthesis 111 comprises two skeletal prosthetic elements 112a and 112b made of stainless steel or titanium in which may be packed a bone-growth supporting material such as hydroxy-apatite (not shown).

The upper plate 112a and lower plate 112b connect together by pop rivets through holes 114 (or by swage locking by tools as shown in Figures 14 and 15 and described below) on adjacent overlapping edges 115,116 and by flaps 118 on one edge of upper or lower plates wrapping around edges 119 on adjacent upper and lower plates. Both upper and lower plates have V-notches 117 for engaging the bone sections either side of the disc to be replaced. Both upper and lower plates are engaged to the vertebrae by screws 117a through holes 120 in the notches 117.

The periphery of each plate 112a,112b is determined by through-etching or ECM in a larger plate. Etching burrs are removed by electro polishing.

The vertebra prostheses 211 of Figures 4 to 9 comprise anchor plates 214a which have a pentagonal

protrusion 215 for engaging the bone sections either side of the gap, and a spacer or connecting member 216 joining the anchor plates 214b.

The spacer member 213 is formed from a single plate of sheet material which is bent into a closed loop and has tabs 217 by which it is clipped together to fit the anchor plates 214 and secured thereto by pop rivets through holes 218 located on upper and lower flaps of anchor plates 214, and upper and lower edges of spacer member 216 or swage locked as described below. The member also has spikes 219 which can penetrate into bone either side of the gap to secure the prosthesis in place. Additional spikes could however be provided on the anchor plates.

The anchor plates 214 and the spacer member 213 are made from sheet material such as stainless steel or titanium by etching or ECM. Figures 7 and 8 show etched plates 241 and 251 respectively from which the anchor plates 214 and the spacer member 213 can be produced by suitable folding or bending.

The plate 241 is etched with fold lines 242 and etched-through lines 243. Pentagonal protrusion 215 is formed by bending the pentangular portions 244 out of the plane of the plate on the fold lines 242. Apertures

for through spikes 219 are made by etching out the portions 245.

The plate 251 is formed with fold lines 252,253.

The periphery of each plate 241 and 251 is determined by through-etching in a larger plate. Etching burrs are removed by electropolishing.

The spacer member 213 is bent from the plate 251 along the fold lines 252 and assembled to fit anchor plate 214 by fitting the tabs 217 through the apertures therein and folding them about the fold lines 253. Not all the tabs and corresponding apertures are shown. The prosthesis is then secured by fastening the anchor plates 214 to the spacer member 213 by pop rivets or swaging through holes 218 as described below.

The prostheses of Figures 1 to 3 and 4 to 7 are intended to be packed with pieces or sticks of hydroxy-apatite 216 prior to closing up the assembly. The result is a strong, rigid prosthesis that can be fixed by the pentagonal protrusions 215 into the neighbouring bone sections to bridge the gap between them and provide a nucleus for bone growth to consolidate the bridge.

Figure 9 shows alternative vertebrate sections 261,262,263 merely to indicate that the surgeon has some degree of latitude in the precise configuration of the prostheses to accommodate different details of individual vertebra through the length of the spinal column.

The prostheses as illustrated in Figures 1 to 3 and 4 to 9 are intended to exemplify the constructional method rather than the actual shape and configuration of prostheses which will in fact be used in surgical procedures. Thus where a prosthesis is intended to replace a disc or a vertebra, it will in general resemble the disc or vertebra it is intended to replace.

Swaging has been mentioned above as an alternative to rivetting. A suitable swage tool 23 is shown in Figure 14 and has a flared head which is oblong or oval in cross section.

The tool 23, as shown in Figure 15, is passed through aligned apertures in the members to be swaged together, which (though not illustrated as such) correspond in shape to the cross-section of the swage tool head. The edge of the distal member's aperture overlaps that of the inner member's aperture. The swage tool is rotated 90° and pulled through, bending the overlapping edge around the edge 20 of the inner member's aperture.

Figures 10 to 13 illustrate a different type of prosthesis suitable for bridging long bones where material has been removed. Figure 10 is a flat processed etched or ECM blank 101 of stainless steel or titanium ready for bending to the cylindrical shape of Figure 11, Figures 12 and 13 being cross sections on the lines XII-XII and XIII-XIII respectively.

The blank 101 is formed with upper and lower double rows of screw holes 102 through which small screws secure the prosthesis to the bone sections to be bridged. The upper and lower edges are shaped around the holes 102 to provide some flexibility, the shaping being "wavy" rather than have sharp corners. Fold lines 103 run from upper to lower edge between panels 104 which are apertured by through cuts 105 and fold lines 106 so that panels 105a can be bent in towards the middle of the prosthesis when it is formed from the blank 101, thus creating a stiff structure of greater strength than the bone.

The inner edges 105b of the panels 105a provide line supports for a hydroxy-apatite insert 107 (Figure 12).

Whilst prostheses of the same general shape and configuration as the illustrated prostheses could be

produced in many different ways, it is desirable, according to the present invention, to make them in such a way that they can be custom-made shortly before or even during the course of the surgical procedure in which they will be used.

The illustrated prostheses are for this reason fabricated from plates of sheet material of stainless steel or titanium by an etching or ECM process in which fold lines are introduced on which the sheet can be bent into the required three-dimensional shape. No machining is needed in this operation, nor any special tools, except possibly for pliers to help in the bending operations where small parts such as spikes and tabs are involved.

Equally important to swift and simple manufacture is, of course, rapid design for the implementation of an etching or ECM operation to produce the required shape on folding. Such can be handled by a CAD/CAM facility as illustrated in Figure 16 in which the required prosthesis is modelled on an image 81 on a screen 82 using suitable CAD techniques which might for example involve a light, magnetic or inductive pen 83 to select features from a screen-displayed menu 84, and draw and dimension the skeletonized image 81. Available image-processing software can perform operations on the

image 81 such as rotation, translation, stretching, reversing, scaling and so on. A light-box 85 is provided to illuminate an X-ray photograph 86 which can be viewed with a CCD camera 87 to produce an image on the screen 82 around which the prosthesis can be sketched using the lights, magnetic or inductive pen 83. Software can, however, also be provided to analyse X-ray images taken from different angles to provide information from which a three-dimensional representation of the fracture site can be computed and from which, in turn, the required prosthesis shape can also be worked out according to algorithms, which might be compiled initially using an expert system, for example.

Software can also be provided then to calculate the size of blank required and to specify the fold lines and other features required to be marked to prepare the blank for etching or ECM so that it will deform into the required shape.

By "marking" is meant, of course, the removal or modification of a resist, which may be a wax coating or a rubber or plastic film adhered to the metal surface to allow an etchant or electrolyte access to the metal at the marked places.

The computer can then control the operation of an X-Y plotter 88 equipped with a tool 89 for marking the blank 51.

The tool 89 can be a blade or a rotary tool, for example a miniature air driven router, or a laser or electric discharge device to melt or vaporize a resist, or a pen or jet printer or air brush applying a reagent or solvent.

The marked blank is then subject to the sequence of operations indicated in Figure 17, namely it is first of all etched or electrochemically machined, then rinsed, then the remaining resist is removed, following which it is re-etched or electro- polished to remove sharp burrs left by the etching process, after which it is again rinsed. The thus prepared plate is now plastically deformed, by hand bending on the fold lines, to its final shape as dictated by the fold lines, following which it is autoclaved to sterilize it ready for use.

Figure 18 shows diagramatically a method of electrochemical machining (ECM). A flat metal electrode 91 (cathode) is aligned opposite the metal blank 93 (anode) which has the resist coating 94 with sections removed as at 95.

The said metal blank 93 and metal electrode 91 are connected to a source of direct current. Arcing is prevented by circulating an electrolyte 96, for example an hydroxide or ionised salt, or a conductive acid such as nitric or sulphuric, between the electrodes. Metal ions are taken into the electrolyte from the blank where the resist layer has been removed creating an etching 98 of the required dimensions.

Thereafter, the metal blank 93 is rinsed and the remaining resist coating is removed before electro polishing and the other steps in Figure 17 to achieve a complete prosthesis.

A different approach is shown in Figures 19 and 20. In Figure 19 the metal blank 93 (anode) has no resist coating whatsoever. In fact the resist coating 94 with marked etching pattern 95 is located on the solid metal electrode 91 (cathode). As described with reference to Figure 18, a current passes between the two electrodes as an electrolytic solution 96 flows therebetween to create an etching 98 in the metal blank 93.

Figure 20 shows a further different approach in which a non-conducting plastic sheet 92 is interposed between the blank 93 and the electrode 91, close to the blank. The sheet 92 is apertured as would be a resist,

by routing, laser or otherwise. It may not always be necessary to circulate the electrolyte using this technique.

An advantage of the improved method described with reference to Figures 19 and 20, which is made clear in Figure 21, is further time saving, since the metal blank is not coated in resist, therefore the time-consuming step of resist removal after etching is avoided.

Although numerous alternative procedures have been described within the context of the invention it is clear that yet further variations and modifications could be adopted which would remain within the overall concept. Thus for example etching or ECM need not be the method of preparation - the plate could be machined by conventional metal processing methods for example using a CAM technique based on the X-Y table such as mechanical, grinding, laser or other cutting tools to produce the fold lines and other features. However, these would require stronger machine tool type equipment to resist cutting forces and ensure accuracy; need change tools to produce lines and holes - an expense and sophistication not suitable to the medical environment which this invention will overcome.

If other materials are used, plastics materials for example, they may be selectively modified otherwise than by etching or cutting, as by UV illumination, low power laser, ultrasonic horn or isotope radiation so as to cause shrinkage along lines on one face or the other that would bring about the required deformation.

A surgical technique for disc or vertebra replacement with the above mentioned prostheses is now described with reference to Figures 22 to 35.

The diseased vertebrate body 191 is first exposed, together with adjacent discs 191a,191b and vertebrae, by surgery (Figure 22). Using a jig 190, a pilot hole is drilled in the healthy vertebra 191b, directly above the said diseased vertebra (Figure 23) and a circular piece of bone 192 cut out to a specific depth. A second pilot hole 193 is drilled in the healthy vertebra, 191c, using jig 190, directly below the said diseased vertebrate body, and a circular piece of bone 194 similarly cut out to a specific depth (Figure 24).

In Figure 25 the drill jig 190 has been removed, the hole edges 192,194 chamfered and the holes cleaned to remove the debris, leaving smooth bevelled holes 195.

The next procedure involves locating a clamp frame 196 into the top and bottom of holes 195 with

hemispherical strips 199 and securing the frame 196 by compressing locking screws 198 into the healthy vertebrate bodies either side of the diseased vertebra (Figure 26).

Once this procedure has been carried out both the upper and lower vertebrate bodies are adequately supported so that the diseased vertebrate body 191 can be safely removed leaving gap 200, along with the adjacent discs 191a,191b (Figure 27).

Once they are removed, a double bladed saw is used to cut through to both holes 195 (Figure 28) to form opposed lateral openings 202. After the debris is removed an upper prosthesis anchor plate 214a is positioned into the upper vertebrate body 203 (Figure 29). The pentagonal protrusion 215a of the said prosthesis is a sliding fit into the bevelled hole 195a.

The anchor plate 214a is then screwed into the upper vertebrate body 203 by screw pins 205.

Figure 30 shows the steps in Figure 29 repeated for the lower prosthesis anchor plate 214b positioned into the lower vertebrate body 206 by sliding the pentagonal protrusion 215b into the bevelled hole 195b and securing by screws 208.

Once both the said upper and lower prosthesis anchor plates 214 are positioned (Figure 31) a column jack 209 is inserted into the said metal pentagonal protrusions and tensioned to enable the upper prosthesis anchor plate to be unclamped by releasing screws 198. The vertebra are then jacked apart (Figure 32) by approximately 2 mm, 200, and the spacer member 213 inserted between the two prosthesis anchor plates. At this point, the member 213 is only partially closed up so that access can be had to its interior.

Once the spacer member 213 is in place, the jack 209 is retracted to original length 200 and the spike projections 219 (see Figure 5) are thus driven into the vertebra (Figure 33). The frame clamp screws 198 of the upper clamp 196 are then recompressed and the jack removed.

After removal of the jack 209 (Figure 34) the far side of the spacer member 213 is fastened to both the upper and lower prosthesis anchor plates by pop rivets in holes 218, access for a rivetting tool being available through the open near side, or by swaging (Figures 14 and 15). Hydroxy-apatite blocks 216 are then placed in the centre cavity of the spacer member 213 as is also indicated in Figure 9.

The hydroxy-apatite filled cavity of the spacer member 213 can now be sealed by closing the front panels of the said member and locking the two panels together with the front locking tabs 217 (Figure 35) with further rivetting or swaging to the anchor plates as required at front holes 218 (Figure 36).

The clamp frame 196 is removed by unscrewing clamp screws 198.

Finally, the top and bottom pentagonal protrusions are filled with hydroxy-apaptite 224 and the hole tabs 244 closed (Figure 37). The fully fastened anchor plates and spacer member now form the finished replacement vertebrate prosthesis.

The diseased vertebra has now been completely replaced by a metal replacement vertebra prosthesis in a safe repeatable manner and it remains only to close up.

In cases where only the disc is diseased, the modofied surgical procedure (based on that outlined above) can be carried out using, instead of the replacement vertebra prosthesis described in Figures 4 to 9, the disc replacement prosthesis described in Figures 1 to 3.

CLAIMS

1. A method for making a prosthesis for use in bridging a gap between two bone sections, characterised by comprising the steps of

a) predetermining the shape of the prosthesis required, and

b) preparing a skeletal prosthetic element to the required shape, in such manner as to provide a support in which bone can grow in the gap.

2. A method according to claim 1, characterised in that the skeletal prosthetic element is packed with a bone-growth supporting material.

3. A method according to claim 2, characterised in that the bone-growth supporting material comprises hydroxy-apatite.

4. A method according to any one of claims 1 to 3, characterised in that the skeletal prosthetic element is of stainless steel.

5. A method according to any one of claims 1 to 3, characterised in that the skeletal prosthetic element is of titanium.

6. A method according to any one of claims 1 to 5, characterised in that the skeletal prosthetic element is made by preparing a sheet material plate for plastic deformation to the predetermined shape and plastically deforming said prepared plate to said shape.

7. A method according to claim 6, characterised in that the plate is prepared with fold lines.

8. A method according to claim 6 or claim 7, characterised in that the plate is prepared by etching.

9. A method according to claim 6 or claim 7, characterised in that the plate is prepared by electro-chemical machining.

10. A method according to claim 8 or claim 9, characterised in that features other than fold lines are prepared by the same method used to prepare the fold lines.

11. A method according to claim 10, characterised in that attachment spikes for engaging the prosthesis with neighbouring bone are so prepared.

12. A method according to claim 10, characterised in that apertures for screws and pins are so prepared.

13. A method according to claim 10, characterised in that the required perimeter of the prosthesis is so produced.

14. A method according to any one of claims 8 to 13, characterised by being prepared for removal of metal by removing a resist layer.

15. A method according to claim 14, characterised by the resist being removed mechanically as by a blade or rotary tool.

16. A method according to claim 14, characterised by the resist being removed by an ultrasonic tool.

17. A method according to claim 14, characterised by the resist being removed by vaporisation as by an electrical discharge or laser.

18. A method according to claim 14, characterised by the resist being removed by selectively applying a chemical reagent or solvent.

19. A method according to any one of claims 8 to 18, characterised in that the plate has metal removed from both faces.

20. A method according to any one of claims 8 to 19, characterised in that apertures are produced by a drill, punch or other purely mechanical means.

21. A method according to any one of claims 8 to 20, characterised in that the plate is electro-polished to remove sharp ridges or burrs.

22. A method according to any one of claims 1 to 21, characterised in that the skeletal prosthetic element is prepared by numerically controlled tool means.

23. A method according to any one of claims 1 to 22, characterised in that the skeletal prosthetic element is prepared according to instructions derived from a programmed computer supplied with data specifying the shape of prosthesis required.

24. A method according to claim 23, characterised in that the computer controls the preparation of a plate from which the skeletal prosthetic element can be fashioned by bending along fold lines.

25. A method according to claim 23 or claim 24, characterised in that the computer includes CAD facility.

26. A method according to claim 25, in which X-ray photographs of the prosthesis site are used in the CAD facility.

27. A method according to any one of claims 1 to 26, characterised in that the skeletal prosthetic element is assembled from a plurality of sub-elements.

28. A method according to claim 27, characterised in that the element is assembled from end caps and a spacer member joining the end caps and formed from a folded plate or plates.

29. A method according to claim 28, characterised in that the spacer member is cruciform and comprises meshing plates.

30. A method according to claim 28 or claim 29, characterised in that the spacer member and one end cap are assembled, then bone-growth supporting material introduced, then the other end cap is attached to contain the said material.

31. Apparatus for making a prosthesis for use in bridging a gap between two bone sections at a prosthetic site, characterised by comprising, in combination

a) means for predetermining the shape of the prosthesis required for the site, and

b) sheet material plate preparation means for preparing such plate for plastic deformation to a skeletal prosthetic element, in such manner as to provide a support in which bone can grow in the gap.

32. Apparatus according to claim 31, characterised by comprising etching means.

33. Apparatus according to claim 31, characterised by comprising electro-chemical machinining means.

34. Apparatus according to any one of claims 31 to 33, characterised by comprising electropolishing means.

35. Apparatus according to any one of claims 31 to 34, characterised in that said preparation means are numerically controlled.

36. Apparatus according to any one of claims 31 to 35, characterised by comprising CAD means providing instructions for the preparation means.

37. Apparatus according to claim 36, characterised by comprising X-ray photograph information input means providing data for the CAD means.

38. A prosthesis, characterised by being made by a method according to any one of claims 1 to 30 or by apparatus according to any one of claims 31 to 37.

39. A prosthesis for use in bridging a gap between two bone sections, characterised by comprising a skeletal prosthesis element adapted to the prosthetic site and adapted to be packed with and to hold a bone-growth supporting material.

40. A prosthesis according to claim 39, characterised by being packed with a bone-growth supporting material such as hydroxy apatite.

41. A prosthesis according to claim 39 or claim 40, characterised by comprising folded sheet material.

42. A prosthesis according to any one of claims 39 to 41, characterised by comprising attachment spikes adapted to engage bone either side of the gap.

43. A prosthesis according to any one of claims 39 to 42, characterised by being assembled from a plurality of sub-elements.

44. A prosthesis according to claim 43, characterised by comprising end caps and a spacer member joining the end caps and formed from a folded plate or plates.

45. A prosthesis according to claim 44, characterised by the spacer member being cruciform and comprising meshing plates.

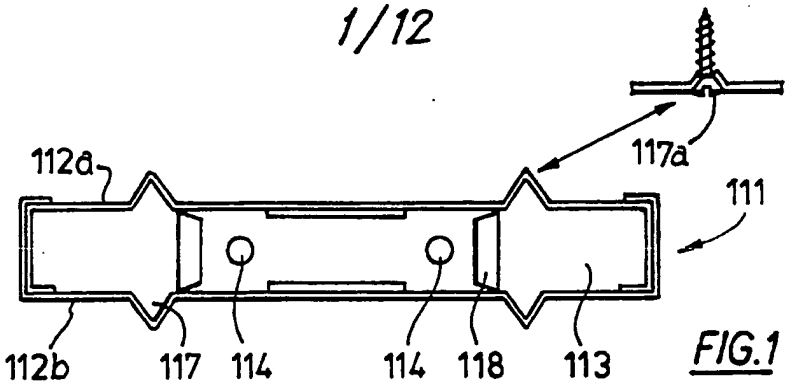

FIG.1

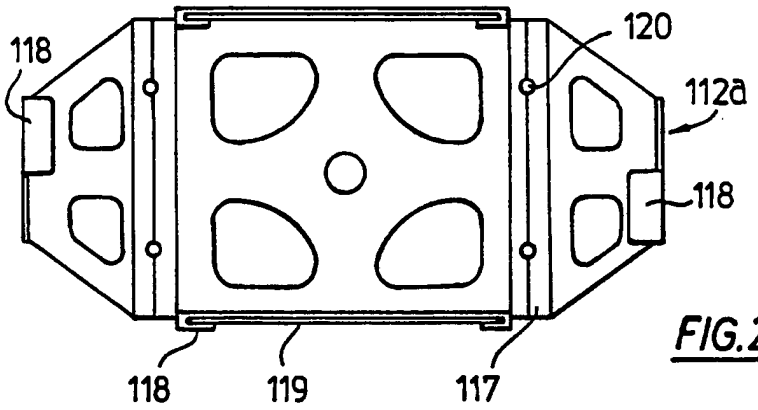

FIG.2

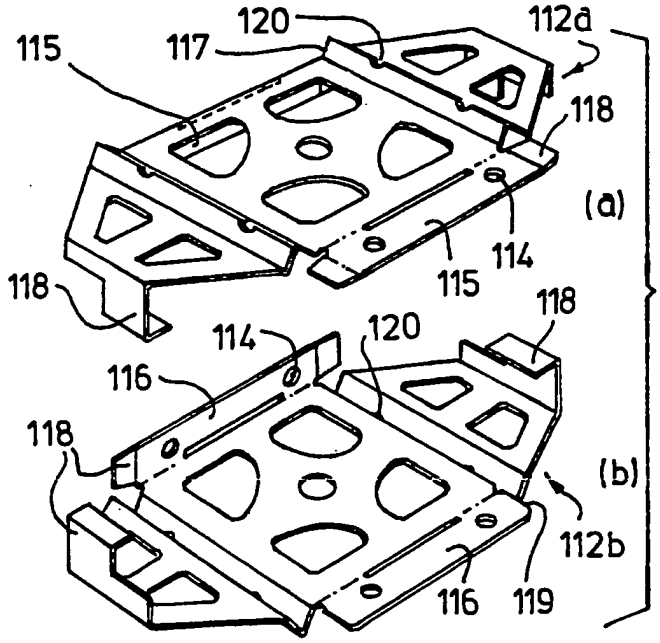

FIG.3

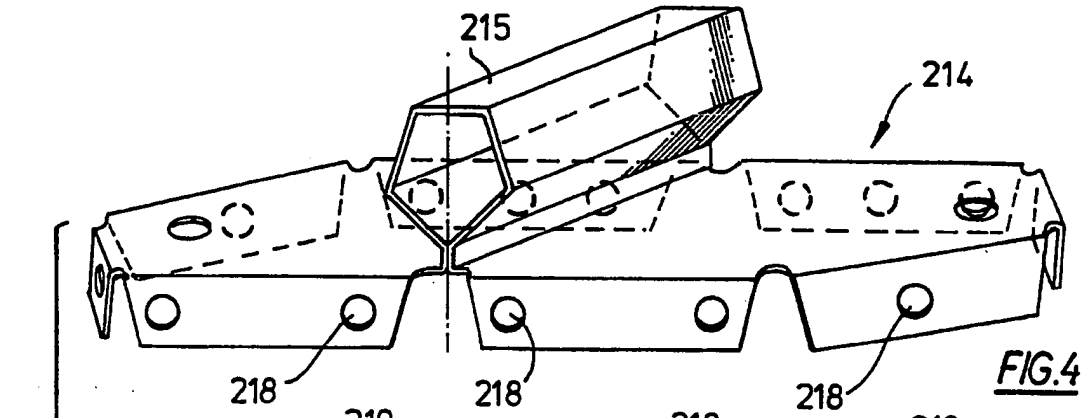

FIG.4

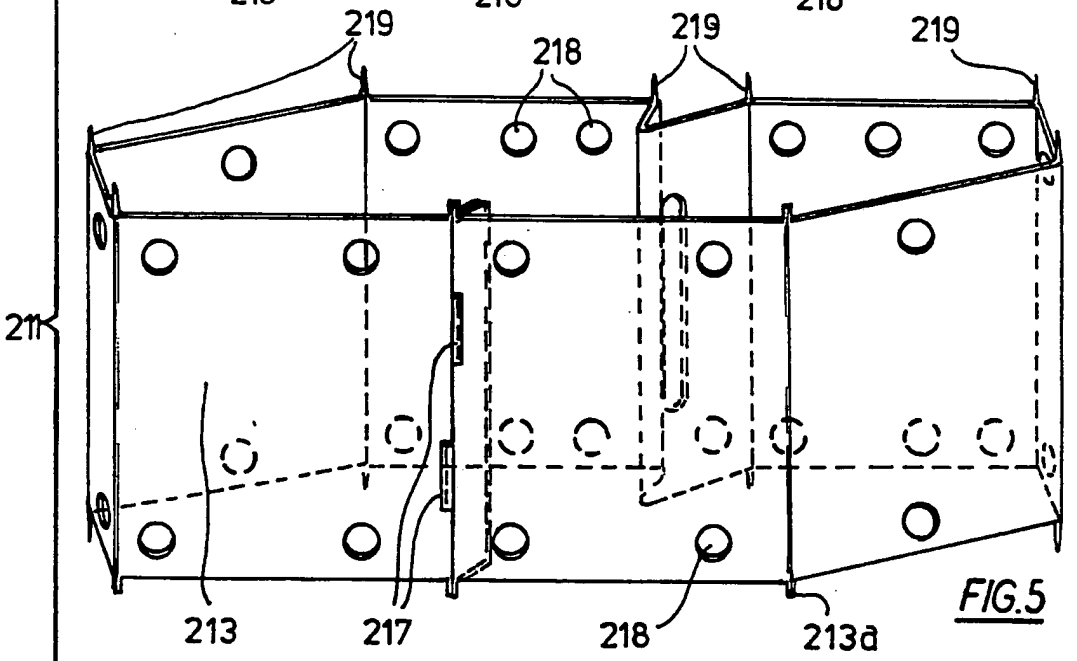

FIG.5

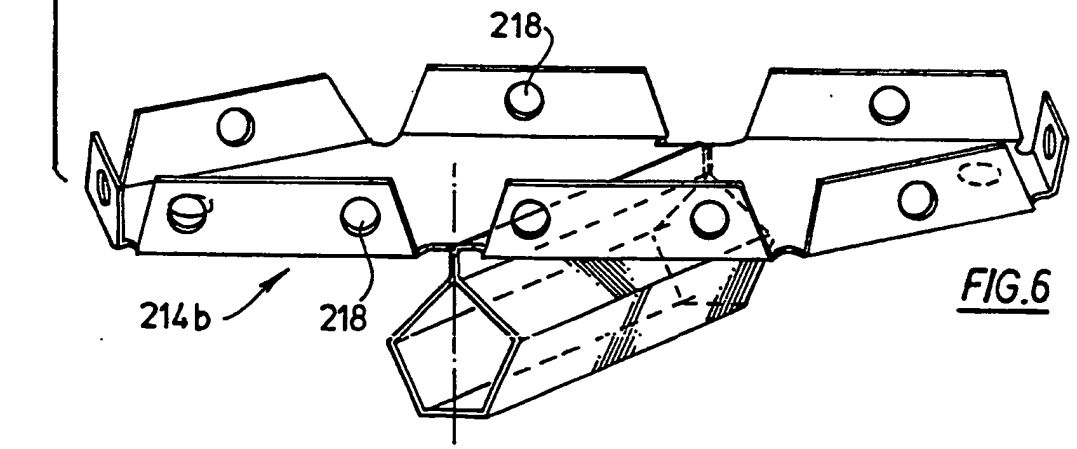

FIG.6

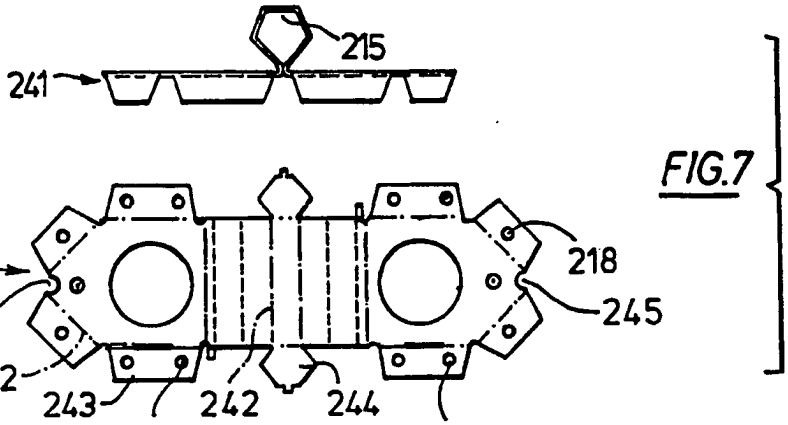

FIG.7

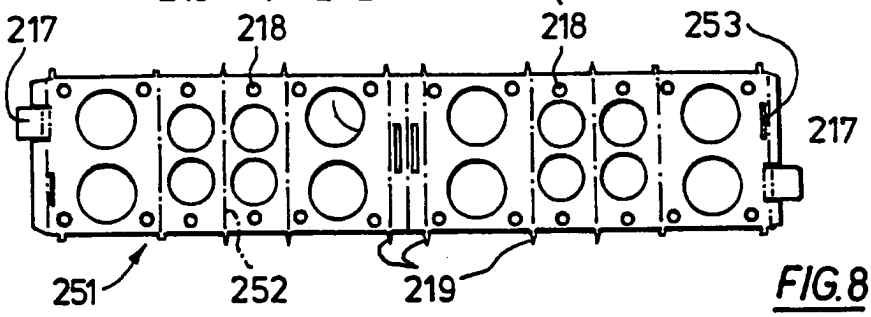

FIG.8

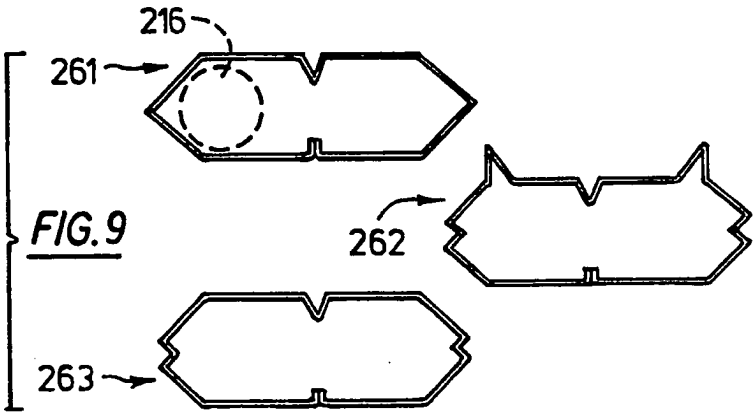

FIG.9

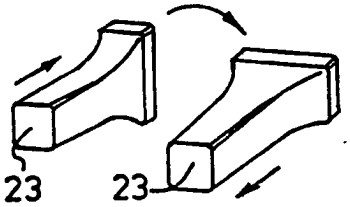

FIG.14

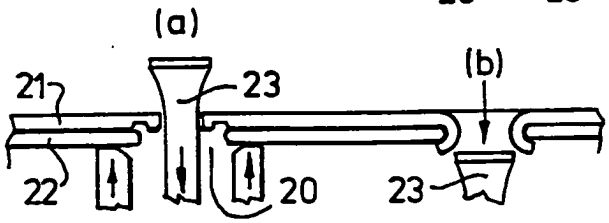

FIG.15

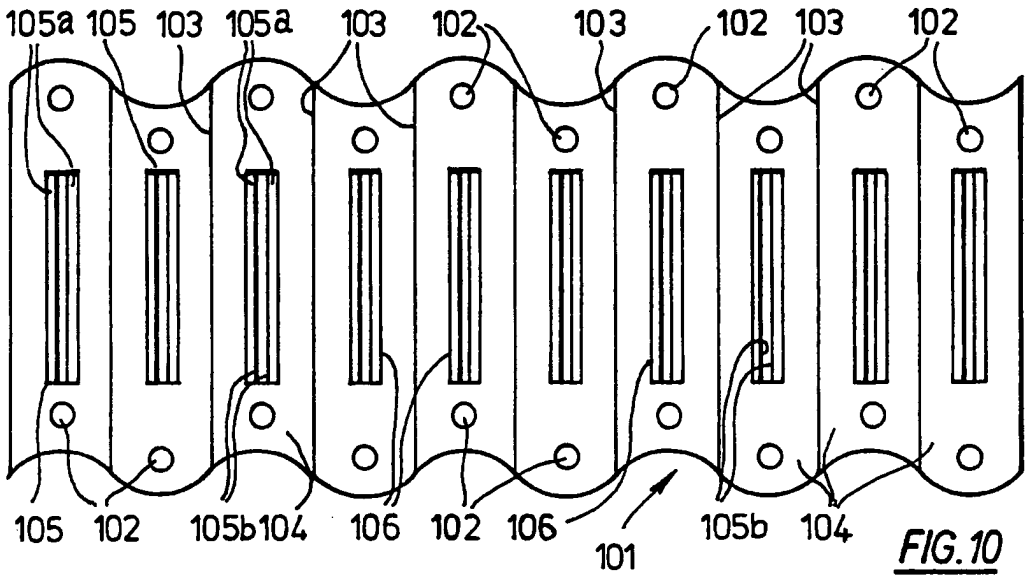

FIG.10

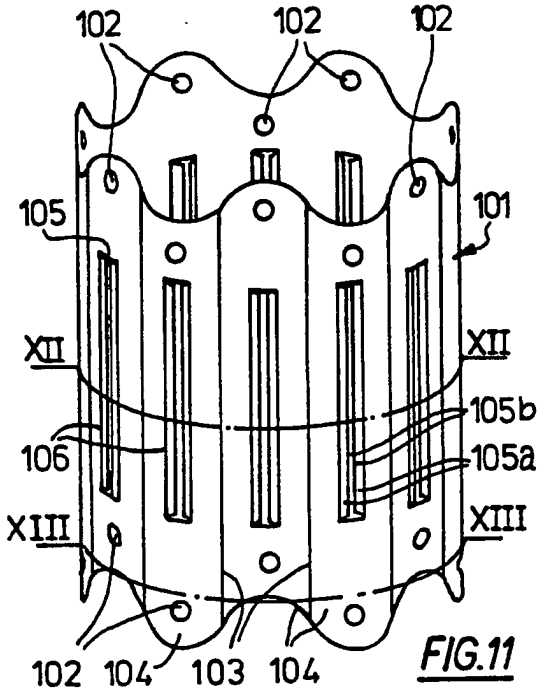

FIG.11

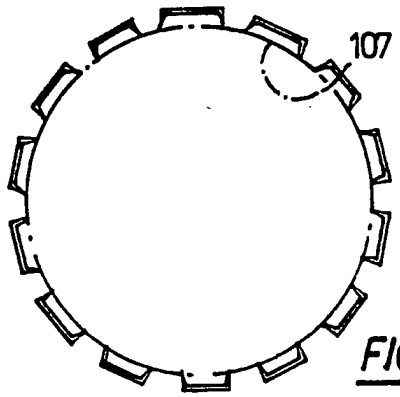

FIG.12

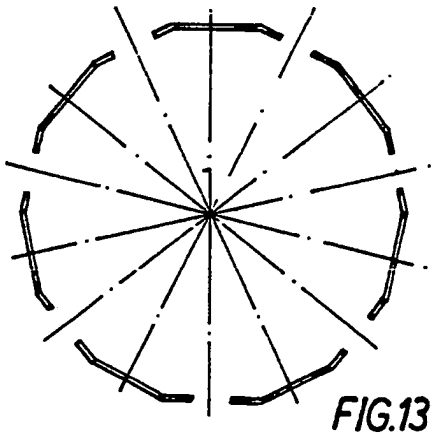

FIG.13

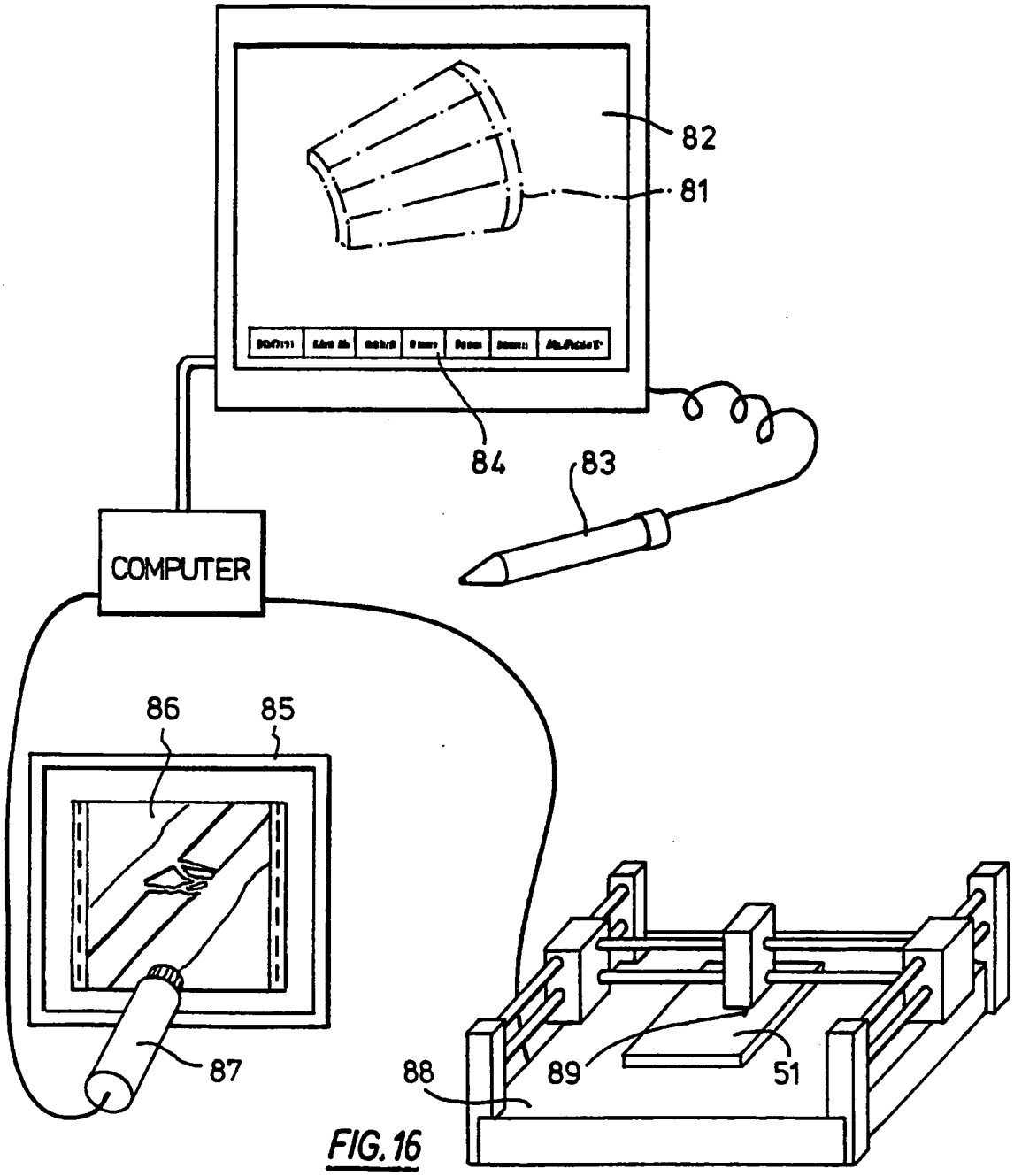

FIG. 16

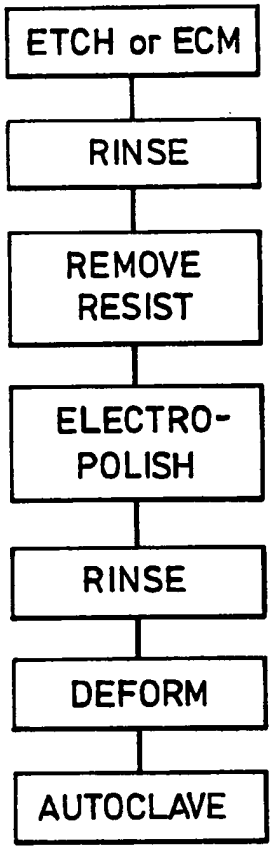
ETCH or ECM
RINSE
REMOVE RESIST
ELECTRO-POLISH
RINSE
DEFORM
AUTOCLAVE

FIG.17

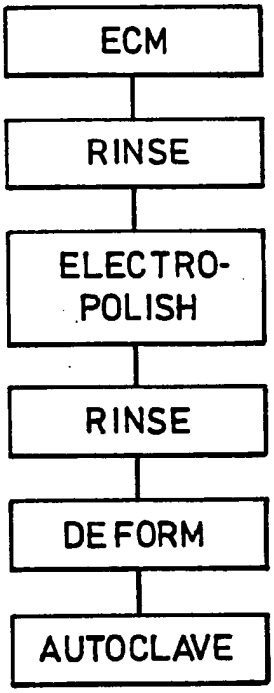
ECM
RINSE
ELECTRO-POLISH
RINSE
DEFORM
AUTOCLAVE

FIG.21

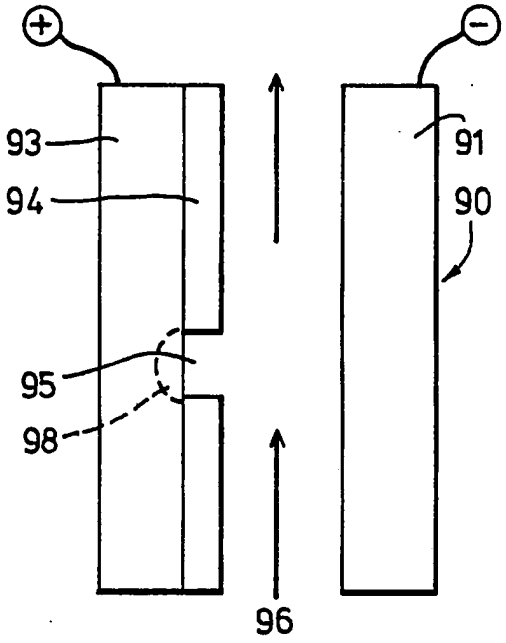

FIG. 18

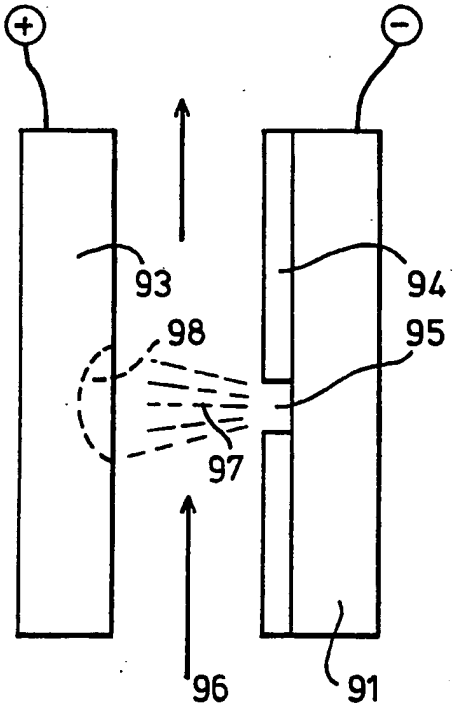

FIG. 19

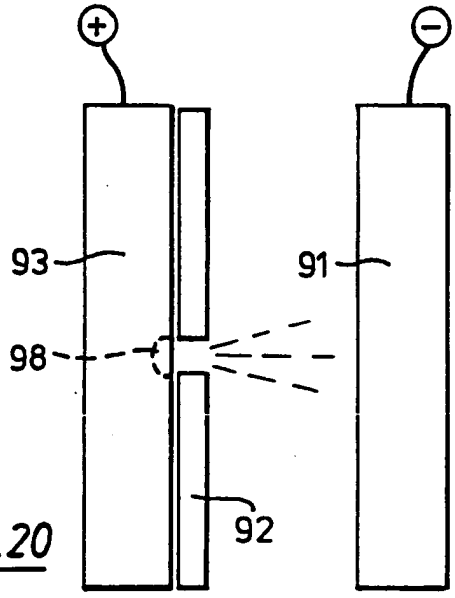

FIG. 20

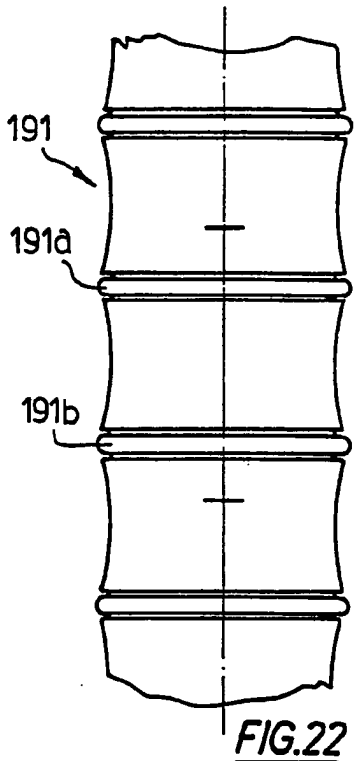

FIG.22

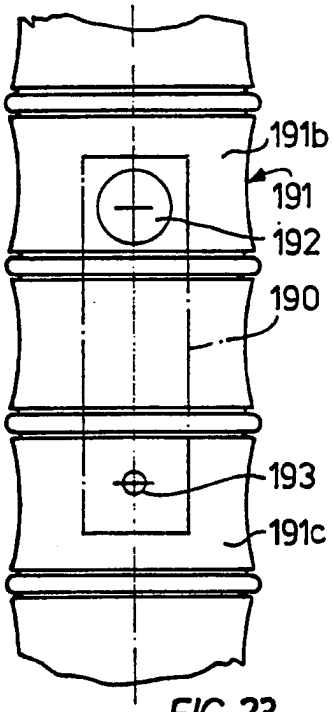

FIG.23

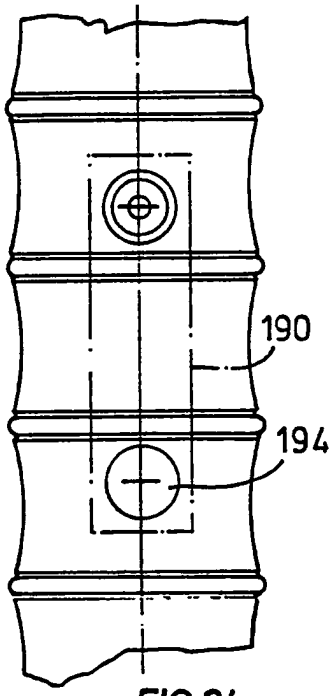

FIG.24

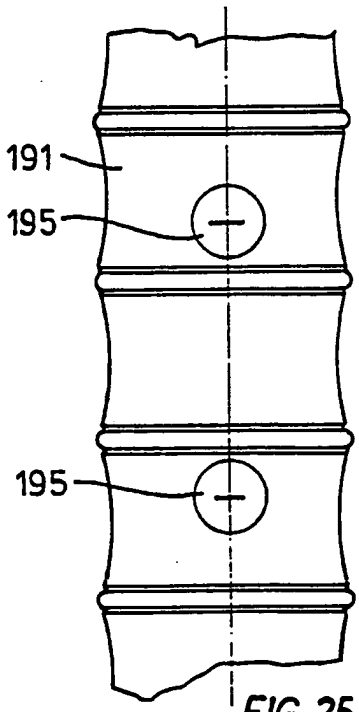

FIG.25

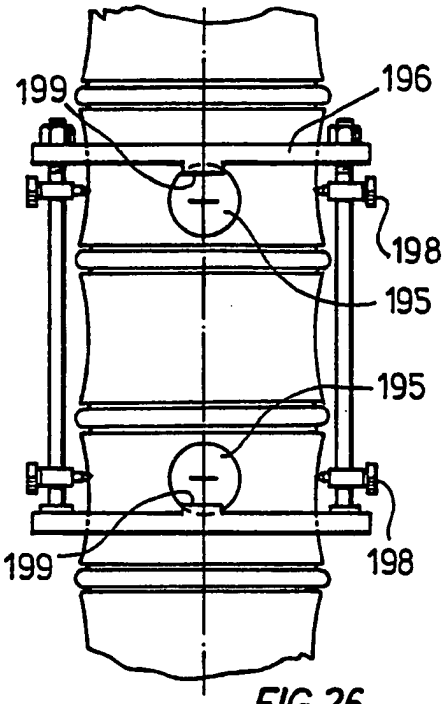

FIG.26

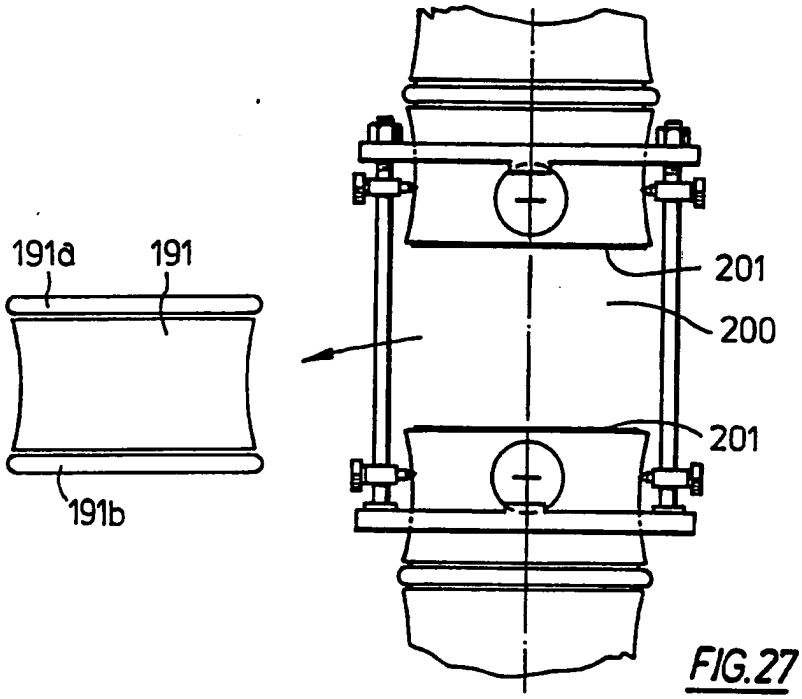

FIG.27

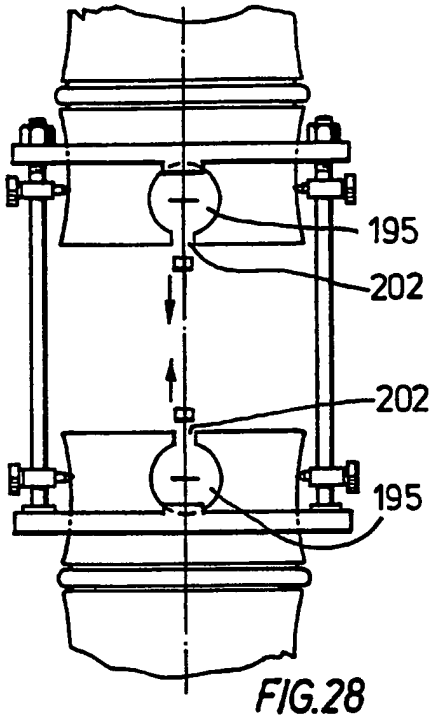

FIG.28

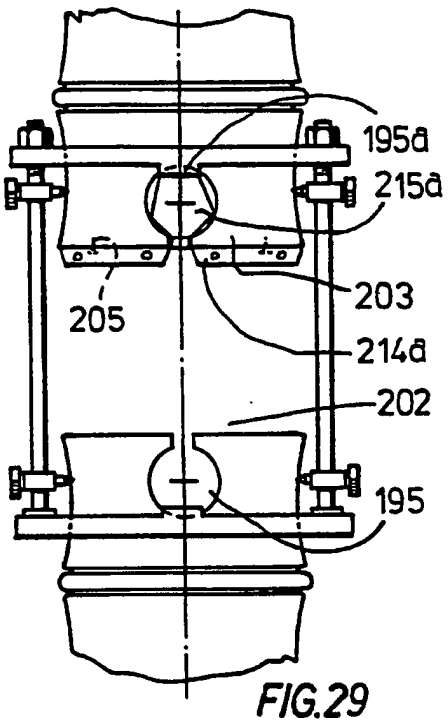

FIG.29

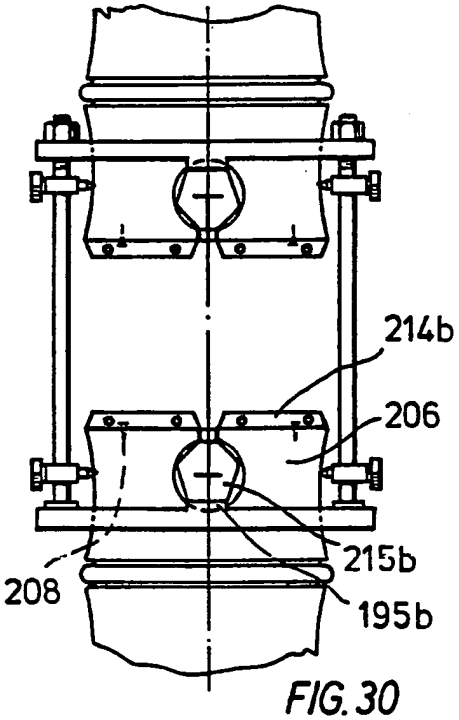

FIG.30

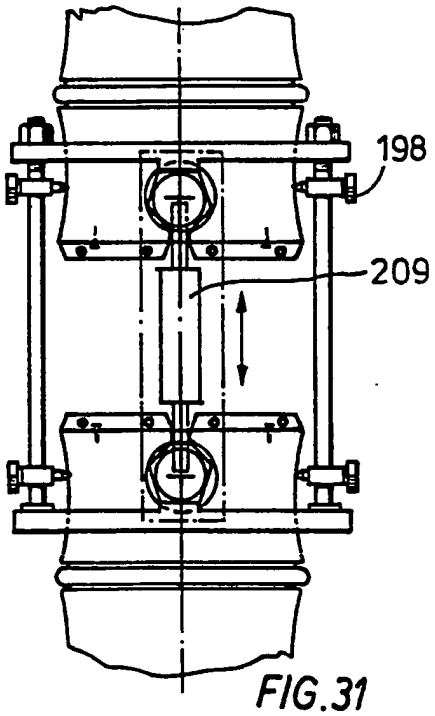

FIG.31

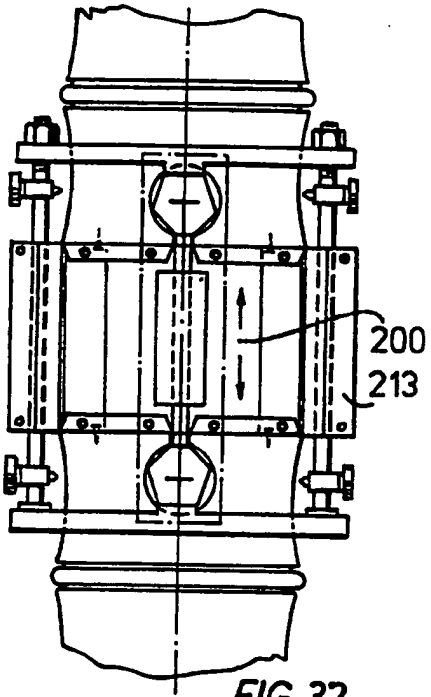

FIG. 32

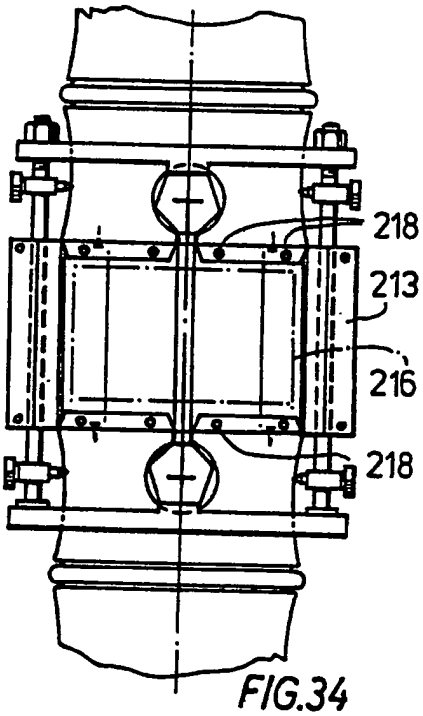

FIG.34

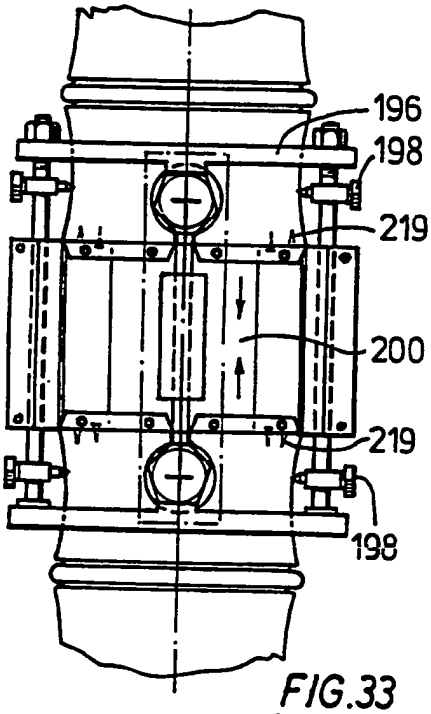

FIG.33

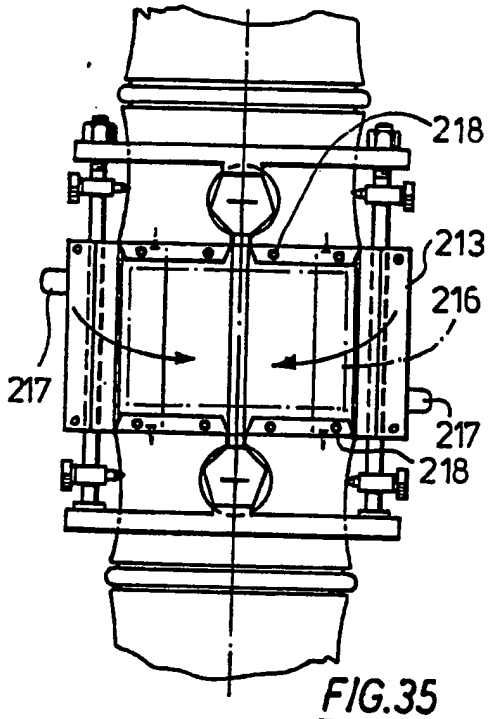

FIG.35

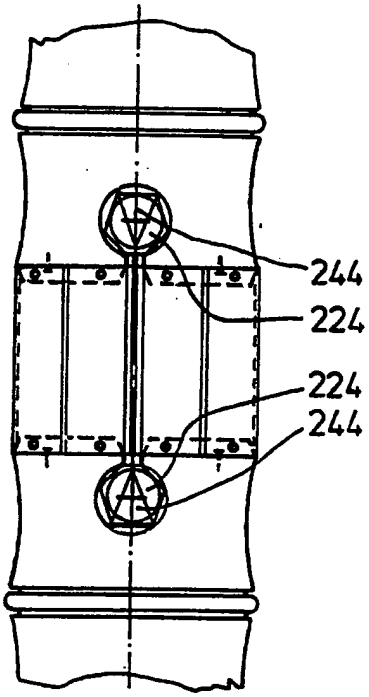

FIG.37

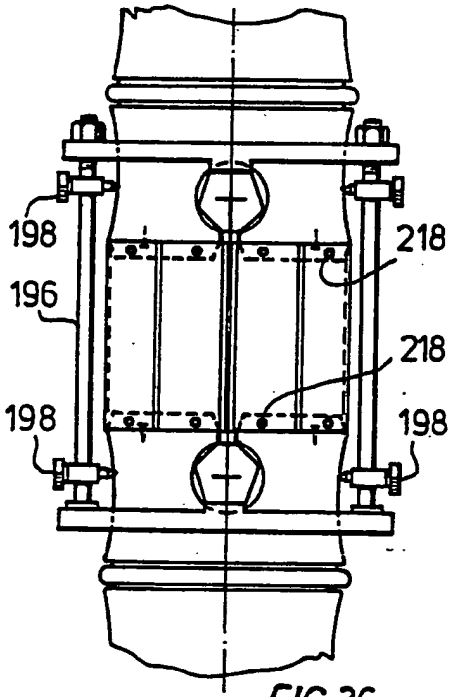

FIG.36

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/01851

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/28; A61F2/44; C23F1/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[9]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	WO,A,8 911 257 (AUGSPURGER) 30 November 1989	1,2,22, 23,25, 27,28, 30,31, 36,38, 39,42-44
A	see abstract see page 1, line 10 - line 18 see page 3, line 4 - page 4, line 2; figures	15,24, 26,35,37

-/--

[9] Special categories of cited documents:[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
24 JANUARY 1992	05. 02. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	KLEIN C. C. Klein

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	WO,A,9 000 037 (MICHELSON) 11 January 1990	1,2,22, 23,25, 27,28, 30,31, 36,38, 39,42-44
A	see page 12, line 1 - line 29 see page 15, line 5 - page 16, line 25; claims 1,10,24; figures 1-3,6-17	11,40
A	WO,A,8 907 910 (CESSOT) 8 September 1989 see the whole document	1,15, 22-25, 31,35,36
A	DE,A,3 522 196 (HAPPEL) 20 February 1986 see abstract	1,22,23, 26,3135, 37
A	WO,A,8 801 517 (MATERIALS CONSULTANTS OY) 10 March 1988 see abstract see page 12, line 30; claim 3; figures 1,2	1-3,30, 38-40
A	US,A,4 501 269 (BAGBY) 26 February 1985 see column 3, line 28 - line 30; figures	4,5
A	DE,A,3 716 026 (S + G IMPLANTS) 1 December 1988 see abstract; figures 1,2	6
A	US,A,4 724 613 (DALE) 16 February 1988 see column 3, line 29 - line 46; claims 2-4; figure	7-10,14, 18,19,32
A	EP,A,0 207 758 (U.C.L.) 7 January 1987	
A	EP,A,0 176 728 (HUMBOLDT) 9 April 1986	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9101851 SA 52635

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 24/01/92

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		DE-A- 3529761	03-07-86
		JP-A- 61122859	10-06-86
		US-A- 4759766	26-07-88

EPO FORM P079

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82